DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005D–0240]

Draft Guidance for Industry on Gingivitis: Development and Evaluation of Drugs for Treatment or Prevention; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled "Gingivitis: Development and Evaluation of Drugs for Treatment or Prevention." The draft guidance is intended to assist sponsors in developing clinical trials for drug products that treat or prevent gingivitis. It addresses specific protocol design elements as well as general concerns about drugs for this indication.

DATES: Submit written or electronic comments on the draft guidance by [*insert date 60 days after date of publication in the* **Federal Register**]. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information (HFD–240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the draft guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to

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http://www.fda.gov/dockets/ecomments. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Frederick Hyman, Center for Drug Evaluation and Research (HFD–540), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–2020.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled "Gingivitis: Development and Evaluation of Drugs for Treatment or Prevention." This guidance is intended to assist sponsors in developing clinical trials for drug products that treat or prevent gingivitis.

Gingivitis, an inflammation of the soft tissues that surround the teeth, is a part of the wider classification of periodontal diseases, which include gingivitis at the milder end and periodontitis at the more severe end. In 1986, FDA approved Peridex (0.12% chlorhexidine gluconate rinse), the first prescription product for gingivitis. In 1997, Colgate's Total toothpaste (0.30% triclosan, 0.24% sodium fluoride) was approved through the new drug application (NDA) process as an over-the-counter (OTC) dentifrice that also has a gingivitis indication. During the past several decades, many products have also entered the marketplace as OTC products that were purported to treat or prevent gingivitis. As a result of the proliferation and promotion of those products, the agency convened a subcommittee of the Dental Products Panel (the Subcommittee) in 1993 to evaluate OTC products that make gingivitis and related claims and that were in the marketplace without an NDA. The Subcommittee's charge was to review the submitted data and to report its findings on the safety and effectiveness of OTC ingredients for the reduction

or prevention of gingivitis. On May 29, 2003, a final subcommittee report was published in the **Federal Register** (68 FR 32232) as an advance notice of proposed rulemaking, the first step in establishing an OTC monograph for these drug products.

Unlike the NDA process that consists of a review of the entire drug product, the monograph process reviews only active ingredients in the class of drug products for safety and efficacy. Until the monograph is finalized, only gingivitis products containing active ingredients that were marketed in the United States before 1975 can continue to be marketed. Any manufacturer attempting to enter the marketplace with a gingivitis product containing an active ingredient that has no prior marketing history in the United States should either petition the developing monograph to consider its inclusion or submit a new NDA for approval before marketing. Sponsors of OTC antigingivitis drugs with active ingredients that the Subcommittee classified as needing further information to make a decision are encouraged to submit further data for review. As a result of these actions, FDA is publishing this guidance document on the development of antigingivitis drugs. The guidance is intended to aid drug sponsors in developing clinical trials either for submitting additional information to the antigingivitis rulemaking, or for gaining approval for a new antigingivitis drug through the NDA process.

This guidance document provides assistance in several ways. It addresses specific design elements such as choosing inclusionary and exclusionary criteria, selecting relevant endpoints, assessing gingivitis, determining the clinical significance of the effect, and collecting meaningful safety data. It also provides comments on general concerns (e.g., prevention versus treatment claims, OTC versus prescription status, special population enrollment, and

nonclinical development issues related to products that are intended for administration within the oral cavity for the treatment or prevention of gingivitis).

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the agency's current thinking on the development and evaluation of drugs for treatment or prevention of gingivitis. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The draft guidance and received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the document at either *http://www.fda.gov/cder/guidance/index.htm* or *http://www.fda.gov/ohrms/dockets/default.htm.*

Dated: 6/22/05
June 22, 2005.

Jeffrey Shuren,
Assistant Commissioner for Policy.

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